

Application No. 10/625,633
Amendment Dated June 23, 2010
Reply to Office Action dated April 14, 2010

REMARKS

The Office Action of April 14, 2010 has been reviewed and carefully considered by the applicants.

Claim Status

Claims 1, 11, and 72 have been amended. None of these amendments are substantive. The application is currently presented with claims 1-3, 5-12, 16, 17, 28, 68, 69, and 71-84.

Claim Rejections under 35 USC §102

Claims 1-3, 5-12, 16, 17, 28, 68, 69, and 71-84 have been rejected under 35 USC §102(e) as being anticipated by Dahlin et al US Published Patent Application No. 2004/0122701 (hereinafter "Dahlin").

In order to anticipate a claim, the cited reference must teach every element of the rejected claim. [MPEP §2131] "A claim is anticipated only if each and every claim as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 Fed. 2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in complete detail as is contained in the claim." Richardson v. Suzuki Motor Co., 868 Fed. 2d 1226, 1236 (Fed. Cir. 1989). The disclosure of Dahlin fails to disclose each and every claim element as set forth in the currently presented claims, particularly independent claims 1, 11, 72, 74, and 76.

Dahlin Reference

Dahlin discloses systems and methods for integrating disease management into a physician workflow. The systems and methods disclosed in Dahlin "integrate disease management into a physician workflow and that can serve as a single point of integration for third party disease management advisor (DMAs)." According to Dahlin, disease management "represents an aspect of data-driven medicine that provides healthcare professionals/practitioners/ providers detailed

instruction for specific situations based on quantitative studies rather than filing a smaller number of more general rules based upon more general studies or experience."

In particular, the Examiner has relied upon the disclosure of Dahlin found at paragraphs [0058, 67-70, 77, and 78] as disclosing all of the features of the currently presented independent claims.

Dahlin discloses the use of treatment algorithms to facilitate communication between disease management advisors (DMAs) and healthcare professionals (HCPs). The treatment algorithm is provided by the DMA and lists "questions the HCP might want to ask" and/or "orders the HCP might want to make." These templates are organized on a per-complaint basis with specific templates for each of common patient complaints. Therefore, the treatment algorithms present actions in the form of questions and orders in response to an identified patient complaint or a physician diagnosis. This is represented in the "best practice treatment advisory" of Fig. 5. The diagnosis of an inner ear infection has been entered into the treatment algorithm and a two step treatment process of erythromycin and keflex is presented.

Therefore, Dahlin discloses a disease management advisor controlled library of best practice information that is presented to a healthcare provider after a diagnosis or patient complaint has been identified.

Claim 1

Claim 1 is directed to a patient physiologic monitoring assembly that includes:

a first logic rule setting including a plurality of logic rules for interpreting the plurality of physiologic variables;

a second logic rule set including a plurality of logic rules for interpreting the physiologic variables; and

a controller that receives said real-time physiologic data stream, said controller including a logic that cross references said plurality of physiologic variables with the first logic rule set and second logic rules set, and generates at least a first diagnostic interpretation of said plurality of physiologic variables utilizing said first logic

rule set and a second diagnostic interpretation of said plurality of physiologic variables utilizing said second logic rule set.

As has been noted in previous responses, the patient physiologic monitoring assembly of claim 1 is a diagnostic aid to a clinician that presents a "differential diagnosis" to the clinician in the form of *a first diagnostic interpretation and a second diagnostic interpretation* that result from the application of two separate logic rule sets to a real-time physiologic data stream. The "treatment algorithm" of Dahlin fails to provide one, no less two, diagnoses based upon physiologic data. Rather, as the name implies, the treatment algorithm identifies a best practice course of treatment after a diagnosis or patient complaint has been identified.

Therefore, the disclosure of Dahlin fails to anticipate the physiologic monitoring assembly of claim 1.

Claims 2, 3, 5-10, and 68 all depend directly and/or indirectly from independent claim 1, which is herein believed to be allowable. Therefore, claims 2, 3, 5-10, and 68 are also believed to be allowable for the reasons stated above, as well as for the subject matter specifically recited in each of these claims. The applicants reserve the right to individually address the patentable subject matter of these claims during further prosecution, if required.

Claim 11

Independent claim 11 is directed to a method for providing diagnostic aid to a clinician monitoring the medical condition of a patient. The method includes:

storing a first and a second set of rule-based algorithms, the first and second sets of rule-based algorithms generating different diagnostic interpretations of the same physiological data;

applying with a logic of a controller at least one rule-based algorithm from the first set of the rule-based algorithms to the acquired physiological data stream;

generating a first diagnostic interpretation with the controller based on the application of the at least one rule-based algorithm from the first set to the acquired physiological data stream;

applying with the logic at least one rule-based algorithm from the second set of rule-based algorithms to the acquired physiological data stream;

generating with the controller a second diagnostic interpretation based on the application of the at least one rule-based algorithm from the second set to the acquired physiological data stream . . .

The method of claim 11 is not anticipated by the disclosure of Dahlin for similar reasons as stated above with respect to claim 1. Additionally, the method of claim 11 includes the feature *the first and second sets of rule-based algorithms generating different diagnostic interpretations of the same physiological data*. This further distinguishes the diagnostic interpretations generated as a result of the claimed method in that the first and second sets of rule-based algorithms are specifically designed to generate different diagnostic interpretations of the same physiological data. Thus, the method of claim 11 provides a diagnostic aid to a clinician by suggesting two alternative diagnoses based upon the available physiological data. Once again, this is contrasted from the disclosure of Dahlin as Dahlin presents best practice courses of treatment and follow-up after a diagnosis or a symptom has been identified by the healthcare provider.

Therefore, claim 11 is not anticipated by the disclosure of Dahlin.

Claims 12, 16, 17, 69, 71, and 84 all depend directly and/or indirectly from independent claim 11, which is herein believed to be allowable. Therefore, claims 12, 16, 17, 69, 71, and 84 are also believed to be allowable for the reasons stated above with respect to claim 11, as well as for the patentable subject recited in each of these claims. The applicants reserve the right to individually address the patentable subject matter of these claims during further prosecution, if required.

Claim 72

Independent claim 72 is directed to a method for diagnosing the medical condition of a patient. The method includes:

applying, with a logic operating on a controller, a first rule set comprising a plurality of rule-based algorithms to the acquired at least one real-time physiological data stream, the first rule set comprising rule-based algorithms directed to producing at least one general diagnostic interpretation of the at least one real-time physiological data stream based on the application of the first rule set;

evaluating with the logic the at least one general diagnostic interpretation to select a second rule set comprising a plurality of rule-based algorithms directed to producing at least one specific diagnostic interpretation;

applying with the logic the selected second rule set to the at least one real-time physiological data stream;

generating with the logic at least one specific diagnostic interpretation of the at least one real-time physiological data stream based on the application of the second rule set . . .

The method of claim 72 is not anticipated by the disclosure of Dahlin for the reasons stated above with respect to both independent claims 1 and 11. Furthermore, the method of claim 72 introduces the feature of *the first rule set comprising rule-based algorithms directed to producing at least one general diagnostic interpretation*. The *at least one general diagnostic interpretation* is used to select *a second rule set comprising a plurality of rule-based algorithms directed to producing at least one specific diagnostic interpretation*. *At least one specific diagnostic interpretation* is generated by the application of *the second rule set* to the physiological data stream.

Therefore, the method of claim 72 further discloses the use of the *general diagnostic interpretation* from the *first rule set* in order to *select a second rule set*. The *second rule set* is applied to the physiological data stream in order to produce *at least one specific diagnostic interpretation*.

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Dahlin not only fails to disclose the generation and presentation of a suggested diagnostic interpretation to a clinician, Dahlin fails to disclose a two tiered approach to the generation of that diagnostic interpretation. As Dahlin fails to disclose the end product of the method, namely a suggested diagnostic interpretation, and also fails to disclose the claimed manner in which that output is achieved, the two tiered approach, Dahlin fails to anticipate the method of claim 72.

Claims 28, 73, and 81-83 all depend directly and/or indirectly from independent claim 72, which is herein believed to be allowable. Claims 28, 73, and 81-83 are also believed to be allowable for the reasons stated above, as well as for the subject matter specifically recited in each of these claims. The applicants reserve the right to individually address the patentable subject matter of these claims during further prosecution, if required.

Claims 74-80

Claims 74-80 are also believed to be allowable for the reasons stated above with respect to independent claims 1, 11, and 72. The applicants reserve the right to individually address the patentable subject matter of these claims during further prosecution, if required.

Conclusion

By the present arguments, the assembly, system, and methods of the current application are believed to be allowable over the disclosure of Dahlin and the rest of the cited references. Specifically, Dahlin fails to provide a single diagnosis, let alone a differential diagnosis to a clinician. Rather, Dahlin receives as an input a clinician diagnosis or symptom identification and returns best practice courses of action in response. Therefore, Dahlin operates as a DMA controlled library of best practice responses.

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The claimed assembly, system, and methods have been shown to be novel and non-obvious over a multitude of references cited by the Examiners in this case. The currently presented claims are believed to be in a condition for allowance. Such action is earnestly requested.

Respectfully submitted,

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A handwritten signature in cursive script that reads "Benjamin R. Imhoff".

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